

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 19

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte DAVID R. ANDREWS,
WILLIAM LEONG, and
ANANTHA SUDHAKAR

Appeal No. 2002-0941
Application No. 09/166,445

ON BRIEF

Before WINTERS, SCHEINER, and GRIMES, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

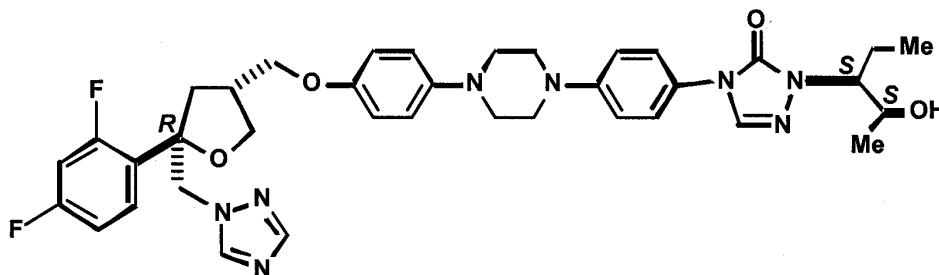
DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 1 through 5, which are all the claims pending in the application.

The Invention

Applicants have discovered that the compound having formula I can exist in the form of three crystalline polymorphs, each distinctly different from each other and from the amorphous form in physico-chemical data, physical properties, and methods of preparation. These crystalline polymorphs are referred to as Form I, Form II, and Form

(1) A crystalline polymorph form I of (-)-4-[4-[4-[4-[(2R-cis)-5-(2,4-difluorophenyl)tetrahydro-5-(1H-1,2,4-triazol-1-ylmethyl)furan-3-yl]-methoxy]phenyl]-1-piperazinyl]phenyl-2,4-dihydro-2-[(S)-1-ethyl-2(S)-hydroxylpropyl]-3H-1,2,4-triazol-3-one represented by formula I



<u>d spacing</u> (± 0.04)	<u>RI</u>
6.10	Medium
4.63	Medium
4.10	Wide
3.69	Wide
3.05	Wide

The Prior Art Reference

In rejecting applicants' claims under 35 U.S.C. § 102(e) and 35 U.S.C. § 103(a), the examiner relies on the following reference:

Andrews et al. (Andrews)	5,625,064	Apr. 29, 1997
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The Rejections

The appealed claims stand rejected as follows:

- (1) claims 1, 2, and 3 under 35 U.S.C. § 112, second paragraph, as indefinite;
- (2) claims 1 through 5 under 35 U.S.C. § 102(e) as anticipated by Andrews; and
- (3) claims 1 through 5 under 35 U.S.C. § 103(a) as unpatentable over Andrews.

Deliberations

Our deliberations in this matter have included evaluation and review of the following materials:

- (1) the instant specification, including all of the claims on appeal;
- (2) applicants' Appeal Brief (Paper No. 17);
- (3) the Examiner's Answer (Paper No. 18); and
- (4) the above-cited prior art reference.

On consideration of the record, including the above-listed materials, we reverse each of the examiner's rejections.

Section 112

In our judgment, claims 1, 2, and 3 set out and circumscribe a particular area with a reasonable degree of precision and particularity; and the examiner's rejection of these claims under 35 U.S.C. § 112, second paragraph, for indefiniteness, lacks merit. We shall not belabor the record with extensive commentary on this point, but simply refer to applicants' discussion in the Appeal Brief, pages 3 and 4, with which we agree. Additionally, the examiner does not invite attention to any language or limitation in claims 1, 2, or 3 which would give rise to a case of indefiniteness.

The rejection under 35 U.S.C. § 112, second paragraph, is reversed.

Section 102(e)

The examiner argues that (1) Andrews describes a compound having formula I illustrated in claim 1 on appeal; and (2) Andrews discloses that that compound possesses antifungal activity. With respect to the particular polymorphic form recited in the appealed claims (crystalline polymorph form I), the examiner acknowledges that "Andrews is silent to [sic] as to nature of crystalline form produced" (Paper No. 18, page 4, first full paragraph). Nevertheless, the examiner would shift the burden of persuasion to applicants to establish that the prior art compound disclosed by Andrews lacks the x-ray powder diffraction pattern and infrared spectrum characteristics recited in applicants' claims ("evidence in verified form is needed that the prior art compound inherently lacks the characteristics relied on" id.). This constitutes reversible error.

As stated in the specification, page 2, second paragraph, applicants have discovered that the compound of formula I can exist in the form of three crystalline polymorphs, each distinctly different from each other and from the amorphous form. These crystalline polymorphs are referred to in the specification as Form I, Form II, and Form III and, according to applicants, Form I is the most stable.

The examiner does not deny that applicants' specification teaches any person skilled in the art how to make crystalline polymorph form I of the compound of formula I illustrated in claim 1 on appeal. Nor can the examiner point to any passage in Andrews disclosing applicants' method for making crystalline polymorph form I, or establishing a reasonable basis for concluding that the prior art compound disclosed by Andrews meets all the limitations of the claims. On the contrary, the examiner acknowledges that "Andrews is silent to [sic] as to nature of crystalline form produced" (Paper No. 18, page 4, first full paragraph).

On these facts, the examiner is not in a position to invoke the principles enunciated in In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596-97 (CCPA 1980); In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977); and In re Swinehart, 439 F.2d 210, 213, 169 USPQ 226, 229 (CCPA 1971). Rather, the facts here more closely resemble those presented to another merits panel of this board in Ex parte Skinner, 2 USPQ2d 1788 (Bd. Pat. App. & Int. 1986). As stated by the board in Skinner:

We are mindful that there is a line of cases represented by In re Swinehart, 439 F.2d 210, 169 USPQ 226 (CCPA 1971) which indicates that where an examiner has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, the examiner possesses the authority to require an applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on. Nevertheless, before an applicant can be put to this burdensome task, the examiner must provide some evidence or scientific reasoning to establish the reasonableness of the examiner's belief that the functional limitation is an inherent characteristic of the prior art. In the case before us, no such evidence or reasoning has been set forward. [id. at 1789]

The rejection under 35 U.S.C. § 102(e) is reversed.

Section 103(a)

Citing Ex parte Hartop, 139 USPQ 525 (Bd. App. 1962), the examiner apparently would invoke a per se rule of obviousness, viz., that merely changing the form, purity, or another characteristic of an old product, the utility remaining the same as that for the old product, does not render the claimed product patentable. The examiner argues that (1) crystalline polymorph form I of the compound of formula I illustrated in claim 1 on appeal is merely a different polymorphic form of the compound disclosed by Andrews having formula I; (2) crystalline polymorph form I recited in applicants' claims and the compound disclosed by Andrews having formula I both possess antifungal activity; and (3) accordingly, the subject matter sought to be patented in claims 1 through 5 would have been prima facie obvious in view of Andrews. We disagree.

First, as stated in In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133

(Fed. Cir. 1995):

The use of per se rules, while undoubtedly less laborious than a searching comparison of the claimed invention--including all its limitations--with the teachings of the prior art, flouts section 103 and the fundamental case law applying it. Per se rules that eliminate the need for fact-specific analysis of claims and prior art may be administratively convenient for PTO examiners and the Board. Indeed, they have been sanctioned by the Board as well. But reliance on per se rules of obviousness is legally incorrect and must cease.

Second, the principle of law enunciated in Ex parte Hartop, 139 USPQ 525 (Bd. App. 1962) has been substantially discredited in In re Cofer, 354 F.2d 664, 667-68, 148 USPQ 268, 270-71 (CCPA 1966).

Third, on this record, the examiner has not adequately explained how a person having ordinary skill would have been led from "here to there," i.e., from the Andrews compound having formula I to the crystalline polymorph form I recited in claims 1 through 5.

The rejection under 35 U.S.C. § 103(a) is reversed.

Conclusion

In conclusion, for the reasons set forth, we do not sustain the rejection of claims 1, 2, and 3 under 35 U.S.C. § 112, second paragraph; the rejection of claims 1 through 5 under 35 U.S.C. § 102(e); or the rejection of claims 1 through 5 under 35 U.S.C. § 103(a).

The examiner's decision rejecting claims 1 through 5 is reversed.

REVERSED

Sherman D. Winters
Administrative Patent Judge

Toni R. Scheiner
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

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) APPEALS AND
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Appeal No. 2002-0941
Application No. 09/166,445

Page 9

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